SENATE DOCKET, NO. 856 FILED ON: 1/16/2019

SENATE . . . . . No. 1206

The Commonwealth of Massachusetts

PRESENTED BY:

Joseph A. Boncore

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act to ensure the fair, transparent and patient-focused use of health technology assessments by the Commonwealth.

PETITION OF:

NAME:	DISTRICT/ADDRESS:
Joseph A. Boncore	*First Suffolk and Middlesex*

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SENATE . . . . . No. 1206

By Mr. Boncore, a petition (accompanied by bill, Senate, No. 1206) of Joseph A. Boncore for legislation to ensure the fair, transparent and patient-focused use of health technology assessments by the Commonwealth. Public Health.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-First General Court
(2019-2020)

An Act to ensure the fair, transparent and patient-focused use of health technology assessments by the Commonwealth.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 118E of the General Laws is hereby amended by inserting after section 12 the following section:

Section 12A. (a) As used in this section, the following words shall have the following meanings unless the context clearly requires otherwise:

"Executive office" means the executive office of health and human services.

"External expert" means an individual who possesses scientific or medical training that the executive office lacks with respect to a disease or therapeutic area that is the subject of a health technology assessment.

"Health technology assessment" means any third-party evaluation of the clinical, economic or public health value of medical innovations, including prescription drugs.

“Prescription Drug” means a drug as defined in 21 U.S.C. section 321(g)(1) and approved by the Federal Food and Drug Administration for the treatment of disease in humans.

"Rare disease” means any disease that affects fewer than 200,000 people in the United States, which has status as an "orphan" disease for research purposes, or is known to be substantially underdiagnosed and unrecognized as a result of lack of adequate diagnostic and research information.

(b) The executive office shall not rely in whole or in part on any health technology assessment to support any negotiations for supplemental rebate agreements with respect to any prescription drug (1) if the third party conducting such health technology assessment has within twenty-four months prior to the completion of the health technology assessment received (i) any funding or other support from any health insurance company, pharmaceutical manufacturing company or pharmacy benefit manager or (ii) more than fifty percent of its total funding from any one source or (2) if the health technology assessment was not conducted and completed independently and free from any collaboration with or influence by the executive office or any other agency, department, board or commission of the commonwealth.

(c) The executive office shall disclose whether it has relied on any health technology assessment in whole or in part as support for supplemental rebate agreement negotiations with respect to a prescription drug thirty days after the commencement of such negotiations through publication on the executive office’s website. Such publication shall include:

(1) the identity of the third party that conducted the health technology assessment;

(2) a complete list of the governance and advisory board members of such third party;

(3) a complete list of all of the third party's sources of funding and funding amounts from each such source;

(4) the identity of the prescription drug that is the subject of supplemental rebate agreement negotiations;

(5) a summary of all reports, records, methodologies, data and all other documents relied upon by the third party in support of the health technology assessment;

(6) a summary of all feedback and other contributions solicited or received by the third party in support of the health technology assessment, including any such feedback and contributions provided by the manufacturer of the prescription drug that is the subject of the health technology assessment to the extent that the manufacturer permits the public disclosure of such information or documentation, and the methodology by which such feedback or other contributions were incorporated, calculated or quantified; and

(7) the identity of any external experts consulted by the third party in support of the health technology assessment and a summary of any expert reports or other information produced by such experts relative to the health technology assessment.

(d) The executive office shall provide advance notice to any manufacturer of a prescription drug that is the subject of any health technology assessment on which the executive office intends to rely in whole or in part in support of supplemental rebate agreement negotiations. Such notice shall be confidential and not a public record under clause twenty-sixth of section 7 of chapter 4 or under chapter 66, and shall be delivered in writing no later than forty-five days prior to the commencement of such negotiations. Such notice shall identify with reasonable detail the health technology assessment on which the executive office intends to rely.

To the extent that such health technology assessment incorporates any non-public model or methodologies, such notice shall provide that documents describing such non-public model or methodologies shall be disclosed in reasonable detail to the manufacturer no later than ten days after a request for such documents is made.

(e) The executive office shall not rely in whole or in part on any health technology assessment in support of any supplemental rebate agreement negotiations with respect to any prescription drug unless such health technology assessment is:

(1) supported by meaningful input from patients and caregivers affected by the condition or disease being studied, and any other input or variables that should reasonably be considered in connection with a fair and balanced health technology assessment, including without limitation caregiver burden, the value of treating patients with unmet medical needs, the severity of the disease being studied, and any other non-health related issues including but not limited to societal impact;

(2) supported by meaningful input from external experts on the following topics, without limitation: (i) the impact of particular coverage, cost-sharing, tiering, utilization management, prior authorization, medication therapy management, or other utilization management policies on adherence by patients to the prescription drug, and on access to the prescription drug; (ii) the demographics and the clinical description of patient populations treated by the prescription drug; and (iii) to the extent the prescription drug is approved for the treatment of a rare disease, the severity of and the unmet medical need associated with the rare disease, the benefits and risks of the prescription drug as a treatment for the rare disease, and factors that may

be limiting access by patients requiring treatment from or consultation with a rare disease specialist; and

(3) validated in writing by third parties unrelated to the third party that conducted the health technology assessment, including without limitation external experts and academics and physicians with knowledge of and expertise in the disease area being studied.

(f) Nothing in this section shall be construed to authorize the executive office to deny access by any Medicaid recipient to any prescription drug that is covered under a Medicaid drug rebate agreement.